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| --- | --- |
| **QUESTIONS** | **ANSWERS** |
| 1. Please provide contact information:
 | Name:  |
| Business Name:  |
| Address:  |
| Phone:  |
| Email:  |
| 1. What tests would you like performed at the study timepoints (Potency, pH, sterility, etc.)? See Below
 |
| Option A:  | Option B: Select Tests and List Timepoints  |
| [ ] **Default to ARL suggested tests**  | Test | Timepoints | Test | Timepoints |
| [ ] Potency |  | [ ] Container Closure |  |
| [ ] Appearance |  | [ ] Antimicrobial Effectiveness |  |
| [ ] pH |  | [ ] Microbial Enumeration |  |
| [ ] Particulate Matter |  | [ ] Preservative Quantitation |  |
| [ ] Sterility |  | [ ] Endotoxin |  |
| 1. Product Description (Drug name(s), concentration(s)):
 |  |
| 1. What is the target beyond use date (BUD)?
 |  |
| 1. What is the formulation identification number?
 |  |
| 1. Please provide any relevant NDC #’s:
 |  |
| 1. cGMP or non-cGMP?
 |  |
| 1. Product Type (solution, suspension, emulsion, etc?):
 |  |
| 1. Please list any antimicrobial preservatives present:
 |  |
| 1. Is this a single or multi-dose container?
 |  |
| 1. What is the route of administration?
 |  |
| 1. Container type, size, and fill volume?
 |  |
| 1. What is the theoretical maximum batch/lot size?
 |  |
| 1. What is the average number of lots produced per month?
 |  |
| 1. Endotoxin limit, or provide the average patient weight and max dose/hour:
 |  |
| 1. Storage Conditions (Room temp, refrigerated, etc.)?
 |  |
| 1. If necessary, list any secondary packaging or overwrap needed for sample storage (brown bags, etc.):
 |  |
| 1. Should Day 0 be the date compounded or the date received by ARL?
 |  |
| 1. Goals of study, comments, or special requests:
 |  |

**\*\*Please include a copy of your formulation sheet including any sub-formulas with your completed questionnaire\*\***